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09/908,975	07/20/2001	Avi Shoshan	25574	6858

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/908,975

Applicant(s)

SHOSHAN ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/02 & 6/03 6) ☐ Other: \_\_\_\_\_

### **FINAL ACTION**

1. Applicant's amendment submitted on September 8, 2003 is acknowledged. Claims 1-2, 5-15, 29, 30, 33-43 have been canceled. Claim 3, 4, 16-28, 31, 32, 44-60 have been withdrawn as being drawn to a non-elected invention. Claims 61-74 have been added and pending in the instant action. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

**This Action is made FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Previous Objections and Rejections***

3. The objection to the specification for lack of priority information on the first page of the specifications is withdrawn in view of applicant's amendment to the specification. The objection to the specification concerning the figure and misspelled word is withdrawn in view of Applicant's amendment to the specification. The objection to the specification concerning the embedded hyperlinks are maintained and discussed below. The claim rejection under 35 USC 112 second paragraph is withdrawn in view of Applicant's cancellation of the claims. The prior art rejections under 35 USC 102 are withdrawn in view of Applicant's cancellation of the claims.

***Specification***

4. Once again, the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 15. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

It is suggested that applicant enable the embedded hyperlinks by removing "http://."

***New Ground of Rejection(s)***

**THE NEW GROUND OF REJECTION(S) WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:**

***Claim Rejections - 35 USC § 112 Second paragraph: Indefiniteness***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 61-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 61-74 are vague and indefinite at the recitation of "selectively hybridizes" in claim 61 because the term has not been clearly define in the specification. The term is a relative one and no frame of reference is given. Additionally the determination or characterization of selective hybridization requires knowledge or disclosure of potential hybridization targets and/or probes in the reaction mixture. None is given or mention; thus the claim is vague, indefinite and incomplete.

***Claim Rejections - 35 USC § 102 (e)***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 61-74 are rejected under 35 U.S.C. 102(e) as being anticipated by Schweighoffer et al. (US 6,251,590 B1, filed March 24, 1998). Regarding claims 61-74, Schweighoffer et al. teach an oligonucleotide library comprising a plurality of oligonucleotides capable of hybridizing to alternative forms of splicing mRNAs typical of a physiological condition (col. 11, lines 14-16) or pathophysiological state or developmental stage (col. 12, lines 8-11 and col. 17, lines 51-53), said library comprising plurality of cDNAs generally double stranded in nature corresponding to RNA regions specific of alternative splicing (col. 10, lines 12-18). Schweighoffer et al. teach wherein the transcribed RNAs (transcriptome) are derived from a cell, tissue, an organ or a biopsy, e.g. cancer biopsy of a sample from a human or mammal source (col. 3, lines 1-8). The reference further teaches wherein the pathological condition is preferably cancer (col. 14, lines 17-51). Schweighoffer et al. additionally teach wherein the library comprising the plurality of oligonucleotides is capable of being overlaid (spotted or coated) on a solid support, such as a chip or biochip (microarray). Therefore, in view of the foregoing, Schweighoffer et al. meets all of the claimed limitations of 61-74 of the instant invention.

***Applicant's traversal***

9. Applicant traverses the rejection on the following grounds: Applicant states that the library described by Schweighoffer are not splice variant set specific but rather designed for the sole purpose of identifying splice variants which are uniquely expressed in pathological tissues.

Applicant states that in order to identify such splice variants, Schweighoffer et al employ oligonucleotide probes which are capable of selectively hybridizing to one splice variant produced from a transcription unit. Applicant concludes that Schweighoffer et al do not anticipate the present invention as claimed.

***Examiner's Response***

10. Applicant's arguments submitted on September 8, 2003 have been fully considered but they are not found persuasive for the reasons that follows: In response to Applicant's arguments that the probes utilized by Schweighoffer are not splice variant set specific but rather designed for the sole purpose of identifying splice variants which are uniquely expressed in pathological tissue , it is noted that that the reference of Schweighoffer et al do teach wherein the oligonucleotides are splice variant set specific. The reference teaches that screening libraries comprises whole set of spliced transcripts produced from a transcription unit in a given condition (col. 9, lines 36-41). Therefore, contrary to Applicant's arguments that Schweighoffer et al employ oligonucleotide probes which are capable of selectively hybridizing to one splice variant produced from a transcription unit, it is noted that Schweighoffer et al. teaches wherein a whole set of splice variant transcripts in a transcription unit of a given condition (col. 9, lines 36-41) are capable of being analyzed. Accordingly, the rejection in view of Schweighoffer et al is maintained.

***Conclusion***

11. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2004, the examiner can be reached at (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

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